K010242

AUG 1 3 2001

Safety and Effectiveness Information

Submitted By: Lisa Hopkins
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, In 47402
(812) 339-2235
January 24, 2001

Device:	Trade Name:	Cook® Zilver™ Biliary Stent
	Proposed Classification Name:	Biliary Catheter and Accessories
Predicate Devices:	Gianturco Biliary Z Stent™	Marketed and distributed by COOK
	Cordis Nitinol Stent & Delivery System	Marketed and distributed by Cordis Corporation
	Symphony Nitinol Stent Transhepatic Biliary System	Marketed and distributed by Boston Scientific

Device Description

The Cook® Zilver™ Biliary Stent is a self-expanding nitinol stent designed for superior radial strength and optimal longitudinal flexibility. Constructed from a series of interconnected Z-shaped segments, the stent conforms to the shape of the biliary system and provides circumferential scaffolding throughout the stent's length. Gold radiopaque markers on each end of the Zilver™ Biliary Stent, along with radiopaque markers on the delivery system, allow precise positioning of the stent. The stent's interconnected Z-shaped segments also keep foreshortening to a minimum.

The stent is supplied preloaded in a 7.0 Fr (OD) sheath delivery system. The stent is deployed with the use of a simple hand held device. The stent is available in unrestrained outer diameters of 6, 7, 8, 9 and 10 mm's and in lengths of 20, 30, 40, 60 and 80 mm's.

Indications for Use

The Cook® Zilver™ Biliary Stent is indicated to maintain patency of a bile duct which is obstructed by tumor or fibrosis.

Substantial Equivalence

The Cook® Zilver™ Biliary Stent is similar to three other biliary stents: The Gianturco Biliary Z Stent®, marketed by COOK, which was found substantially equivalent under FDA DC #K921191, The Cordis Nitinol Stent and Delivery System, marketed by Cordis, which was found substantially equivalent under FDA D.C. #K980823, and Boston Scientific's Symphony Nitinol Stent Transhepatic Biliary System, cleared under FDA D.C. #K963254.

The similar indications for use and technological characteristics of the Cook® Zilver™ Biliary Stent as compared to these predicate devices support a determination of substantial equivalency.

Test Data

The Cook® Zilver™ Biliary Stent was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests include:

- Bench Deployment Testing of Stents: Zilver™ Delivery System
- Radial Force Testing of Zilver™ Stents and Z-Stents®
- Bench Deployment Testing of Stents: Zilver™ Stents and Z-Stents®
- Electrochemical Corrosion Testing of Zilver™ Stents and Z-Stents® at 37° C
- Tensile Test of Zilver™ Stent Axial Bars
- Tensile Test of the Zilver™ Delivery System (120 cm)
- Biocompatibility Testing

The results of these tests provide reasonable assurance that the Zilver™ Biliary Stent has been designed and tested to assure conformance to the requirements for its use as a biliary stent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 3 2001

Ms. Lisa Hopkins
Regulatory Affairs Coordinator
Cook® Incorporated
P.O. Box 489
Bloomington, Indiana 47402-0489

Re: K010242
Cook® Zilver™ Biliary Stent
Dated: May 14, 2001
Received: May 15, 2001
Regulatory Class: II
21 CFR §876.5010/Procode: 78 FGE

Dear Ms. Hopkins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* This response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally §809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010242

Device Name: Cook® Zilver™ Biliary Stent

FDA's Statement of the Indications For Use for device:

The Cook® Zilver™ Biliary Stent is indicated for use in the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010242